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In Re: Patent Term Extension
Application for
U.S. Patent No. 4,911,932

ORDER TO SHOW CAUSE

This is an order to show cause based on the apparent ineligibility of U.S. Patent No. 4,911,932 ("the '932 patent") for patent term extension under 35 U.S.C. § 156.

Factual Background

1. The '932 patent granted on March 27, 1990.

2. The Food and Drug Administration ("FDA") approved New Drug Application ("NDA") No. 21-026 on February 16, 2006, for commercial marketing or use for the human drug product, VUSION® (miconazole nitrate, zinc oxide and white petrolatum).

3. On April 5, 2006, the patent owner, Johnson & Johnson Consumer Companies, Inc. ("Applicant") filed an Application for Extension of Patent Term Pursuant to 35 U.S.C. § 156 ("PTE") for the term of the '932 patent in the United States Patent and Trademark Office ("USPTO") based on the regulatory review period under section 505 of the Federal Food Drug and Cosmetic Act ("FFDCA") of the human drug product VUSION® having the active ingredients miconazole nitrate, zinc oxide and white petrolatum.

4. On September 7, 2006, the USPTO sent an initial letter to FDA requesting their assistance in confirming that VUSION® (miconazole nitrate, zinc oxide and white petrolatum) was (1) subject to a regulatory review period; (2) that the permission for commercial marketing or use was the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred and; (3) that the application was submitted within the sixty-day period following approval of the product with the count of that sixty day period beginning on the date of approval.

5. On December 19, 2006, Applicant filed a request for an interim extension pursuant to 35 U.S.C. § 156(e)(2) because the patent for which extension was sought, the '932 patent, would expire before processing of the application for PTE would be completed.

6. On March 15, 2007, the USPTO granted an interim extension according to 35 U.S.C. § 156(e)(2), because the Director had determined that based on the review of the PTE to date, the patent was eligible for extension.

7. On March 29, 2007, FDA responded to the USPTO's September 7, 2006 letter indicating that VUSION® (miconazole nitrate, zinc oxide and white petrolatum) was subject to a regulatory review period before its commercial marketing or use as required under 35 U.S.C. § 156(a)(4). The FDA's letter also indicated that the PTE application was timely submitted to the USPTO. The letter from FDA stated that two of the active ingredients of VUSION® namely, miconazole nitrate and zinc oxide, had been previously reviewed under section 505 of the FFDCA and previously granted permission for commercial marketing or use, but that white petrolatum had not previously been subject to a regulatory review period under section 505 of the FFDCA , although white petrolatum had been approved for commercial marketing as an inactive ingredient in drug products which had been reviewed under section 505 of the FFDCA.

8. On June 12, 2007, the USPTO sent a letter to FDA requesting that the agency determine the applicable regulatory review period for VUSION® (miconazole nitrate, zinc oxide and white petrolatum) and publish the findings in the *Federal Register* pursuant to 35 U.S.C. § 156(d)(2)(A)(ii).

9. On November 12, 2007, Applicant filed a second request for an interim extension pursuant to 35 U.S.C. § 156(e)(2), because the previously granted interim extension for the '932 patent would expire before processing of the PTE would be completed.

10. On March 14, 2008, the USPTO granted a second interim extension according to 35 U.S.C. § 156(e)(2), because the Director had determined that based on the review of the PTE to date, the patent was eligible for extension.

11. Following grant of the second interim extension pursuant to 35 U.S.C. § 156(e)(2), the USPTO considered that the letter of March 29, 2007, from FDA raises a question of eligibility for patent term extension of the '932 patent.

Eligibility Analysis

The Federal Circuit in *Arnold P'ship v. Dudas*, 70 U.S.P.Q. 2d 1311 (Fed. Cir. 2004), addressed the same eligibility issue present here, i.e., the statutory language of Section 156(f) requires that when a drug product has multiple active ingredients, eligibility of the product for extension is analyzed on a component-by-component basis. Specifically, the Federal Circuit reasoned that the statutory language requires the court to examine the drug product patent's eligibility for extension on a component-by-component basis, not as a whole. *Id.* at 1314. Furthermore, the court explained that "to extend the term of a patent claiming a composition comprising A and B, either A or B must not have been previously marketed. In other words, at least one of the claimed active ingredients must be new to the marketplace as a drug product." *Id.* at 1314. In other words, at least one of A or B must meet the requirement of 35 U.S.C. 156 (a)(5)(A), which requires that the permission for commercial marketing or use of the product (either A or B) after such regulatory review period is the first permitted commercial marketing or use of the product

under the provision of law under which such regulatory review period occurred

Applying this explanation to the PTE for VUSION®, at least one of miconazole nitrate, zinc oxide or white petrolatum must **not** have previously been subject to a regulatory review period and must not have previously been granted permission for commercial marketing or use under the same provision of law under which the regulatory review period of VUSION® occurred. Each active ingredient of VUSION® is separately analyzed for eligibility purposes consistent with the interpretation set forth in *Arnold P'ship Inc. v. Dudas,* as explained *supra*.

(1) Miconazole Nitrate

Applicant acknowledges in their PTE, on page 5, that miconazole nitrate had been previously granted permission for commercial marketing or use after regulatory review under section 505 of the FFDCA. The March 29, 2007 letter from FDA confirms that miconazole nitrate was previously granted permission for commercial marketing or use under section 505 of the FFDCA where the letter states:

> Our records also indicate that two of the active ingredient of Vusion (miconazole nitrate and zinc oxide) do not represent the first permitted commercial marketing or use of the product as defined under 35 U.S.C. § 156(f)(1), and . . . .

Therefore, because miconazole nitrate was previously granted permission for commercial marketing or use under section 505 of the FFDCA, grant of permission for commercial marketing or use of miconazole nitrate in VUSION® cannot serve as the basis for compliance with 35 U.S.C. § 156(a)(5)(A).

(2) Zinc Oxide

Applicant asserts in their PTE, on page 6, that zinc oxide has not been previously approved for commercial marketing or use as a single entity or in combination with another active ingredient under section 505 of the FFDCA and cites to the absence of zinc oxide, as an active ingredient, in search results from the Electronic Orange Book[1].

Although not found in the Electronic Orange Book, the March 29, 2007 letter from FDA indicates that zinc oxide was previously reviewed under section 505 of the FFDCA and granted permission for commercial marketing or use, and therefore, the approval of VUSION® does not constitute the first permitted commercial marketing or use of the product (zinc oxide) as defined under 35 U.S.C. § 156(f)(1). Attached hereto is a list from FDA's internal database indicating several approved NDAs having zinc oxide as an active ingredient (**EXHIBIT 1**) where the NDAs were approved under the same provision of law as VUSION®, i.e., section 505 of the

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[1]The electronic Orange Book is found at: http://www.fda.gov/cder/ob/default.htm.

FFDCA.

Therefore, because zinc oxide was previously granted permission for commercial marketing or use under section 505 of the FFDCA, grant of permission for commercial marketing or use of zinc oxide in VUSION® cannot serve as the basis for compliance with 35 U.S.C. § 156(a)(5)(A).

(3) White Petrolatum

Applicant asserts in their PTE, on page 6, that white petrolatum has not been granted permission for commercial marketing or use as a single entity or in combination with another active ingredient under section 505 of the FFDCA and cites to the absence of white petrolatum, as an active ingredient, in search results from the Electronic Orange Book.

The March 29, 2007 letter from FDA confirms that white petrolatum has NOT been previously approved under section 505 of the FFDCA where the letter states:

> We have no records that the third ingredient, white petrolatum, has been previously approved under section 505 of the Federal Food, Drug, and Cosmetic Act as an active ingredient in a drug product, but it has been approved for commercial marketing as an inactive ingredient in drug products approved under section 505.

Therefore, because white petrolatum had NOT been previously approved for commercial marketing or use under section 505 of the FFDCA, grant of permission for commercial marketing or use of white petrolatum in VUSION® can serve as the basis for compliance with 35 U.S.C. § 156(a)(5)(A).

In order to reach compliance with 35 U.S.C. § 156(a)(5)(A), the preamble paragraph, Section 156(a), states:

> the term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent. . . .

Thus, whether a single component of a multi-component drug product constitutes the first permitted commercial marketing or use (compliance with section 156(a)(5)(A)) is a statutory requirement which is predicated on compliance with a threshold statutory inquiry of whether the patent claims the product (compliance with section 156(a)).

In a Commissioner decision from September 1, 1989, the USPTO determined, in *In re Alcon*, 13 U.S.P.Q.2d (BNA) 1115 (Comm'r Pat. 1989), that eligibility of a patent for patent term extension, based on the regulatory review of a combination active ingredient human drug product, requires that the patent must claim the active ingredient which gives rise to the eligibility. In *Alcon*, the eligibility of the patent for extension based on the regulatory review

period for Tobradex (a combination of tobramycin and dexamethasone) turned (at least in part) on how the combination product was claimed in the patent and whether the product, as claimed, complied with section 156(a)(5)(A). The decision explains that a patent claim would cover Tobradex within the meaning of section 156(a) if it claimed:

> 1) tobramycin alone [single entity];
> 2) dexamethasone alone [single entity]; or
> 3) the mixture of tobramycin and dexamethasone [active ingredient. . .in combination with another active ingredient.]

Id. at 1119. In *Alcon*, to determine whether the active ingredient in the patent [tobramycin] would give rise to eligibility for extension, the decision inserted the definition of "product" from section 156(f) into the statutory requirement in section 156(a)(5)(A) as follows:

> . . .the permission for the commercial marketing or use of [the active ingredient. . . , as a single entity [tobramycin] or in combination with another active ingredient] after such regulatory review period [Tobradex] is the first permitted commercial marketing or use of [the active ingredient. . . , as a single entity (tobramycin) or in combination with another active ingredient] under the provision of law [§ 507of the Act] under which such regulatory review period occurred.

Id. at 1119. In *Alcon*, the active ingredient claimed in the patent, tobramycin, was previously granted permission for commercial marketing or use under the same provision law under which the regulatory review period for Tobradex occurred (section 507 of the FFDCA) and hence, could not give rise to eligibility of the patent for extension. Since Tobradex is a combination product, the other active ingredient, dexamethasone, could have given rise to eligibility of the patent for extension if (1) the patent claimed dexamethasone and (2) dexamethasone had not been previously granted permission for commercial marketing or use under section 507 of the FFDCA. Because the patent for which extension was sought based on the regulatory review period of Tobradex failed to claim dexamethasone, the patent was not eligible for extension. Specifically, the decision states,

> The fact that the other active ingredient [dexamethasone] in Tobradex had not been previously permitted to be commercially marketed or used under § 507 of the Act does not give rise to eligibility, because dexamethasone is not claimed in the patent.

Id. at 1119.

Applying the *Alcon* rationale to the present PTE, the '932 patent would meet the threshold statutory inquiry of whether the patent claims the product if the '932 patent claimed:

> 1) miconazole nitrate alone [single entity];
> 2) zinc oxide alone [single entity]

3) white petrolatum alone [single entity]
4) the mixture of miconazole nitrate, zinc oxide and white petrolatum [active ingredient . . .in combination with another active ingredient.]

In the '932 patent, claims 1 and 2 are directed to a skin care composition comprising as the active ingredients, miconazole nitrate and zinc oxide, and claims 3 and 4 are directed to a method of using the skin care composition having miconazole nitrate and zinc oxide as active ingredients present in the composition in specified ratios. Just as in *Alcon*, the one active ingredient of the combination of active ingredients in the human drug product, white petrolatum, which has not been previously granted permission for commercial marketing or use cannot give rise to eligibility for extension for the '932 patent because the patent does not claim white petrolatum.

It is understood that the '932 patent uses "open" claim language. As such, if a party other than the patent owner made, used, offered to sell or sold VUSION® the party may infringe the '932 patent. Analysis with respect to infringement is irrelevant to a determination of whether the patent "claims" the product. The issue of whether a patent claims a product, within the meaning of 156(a), was addressed, although in a different context, in *Hoechst-Roussel Pharmaceuticals Inc. v. Lehman*, 42 U.S.P.Q.2d 1220 (Fed. Cir. 1997).

In *Hoechst*, the court explained that the concept of a claim is not the same as the concept of infringement. Specifically, the court opined that:

> . . . in order for a patent to "claim" a product, the patentee must have satisfied numerous tests of patentability, including, *inter alia*, a disclosure of the best mode of making the claimed product, and a description which would enable a person skilled in the art to make and use the claimed invention. . . . Direct infringement consists of making, using, offering to sell or selling the invention defined by the claims of a patent, without the authority of the patent owner. See 35 U.S.C. Section 271. With respect to direct infringement, then, the claims define the patent owner's rights whereas infringement is the act of trespassing upon those rights. The relationship between infringement and the claimed becomes even more tenuous. . . . In sum, the concept of a "claim" is different from the concept of infringement, and, as a result, the plain meaning of "claims" is not the same as the plain meaning of infringement.

Id. at 1223.

In the present case, because the '932 patent does not claim white petrolatum, which is the only active ingredient of the multi-component drug product VUSION® which had not been previously granted permission for commercial marketing or use under the provision of law under which such regulatory review period occurred, the patent appears to be ineligible for extension pursuant to section 156.

Interim Extensions

Since the USPTO has made an assessment that the '932 patent appears to be ineligible for extension (as evidenced by the current show cause order), the interim extensions previously granted under section 156(e)(2) would appear to have been improvidently granted and therefore should be vacated *ab initio*. See In re Alcon, 13 USPQ 2d 1115, 1123 (Comm'r Pat. & Trademarks 1989) (stating that "an interim extension can be granted only in those circumstances, unlike the present case, where the Commissioner has determined that the patent is eligible for extension); see also In re Reckitt, 230 USPQ 369 (Comm'r of Pat. & Trademarks 1986) (recognizing that if a patent is ineligible for a patent term extension, then any interim extension granted to maintain a patent during the eligibility review process would be invalid); U.S. Pat. & Trademark Off., Manual of Patent Examining § 2755.01 (8th ed. 2001, rev. Oct. 2005) ("Where a determination is made that the patent is not eligible for patent term extension, an interim extension of the patent term is not warranted under § 156(e)(2). . . . Where an interim extension has been granted and it is subsequently determined that the patent is not eligible for patent term extension, the interim extension may be vacated *ab initio* as ineligible under § 156(e)(2)."). Furthermore, the Federal Circuit in *Somerset Pharmaceuticals Inc. v. Dudas*, 84 U.S.P.Q.2d 2023, 2024 (Fed. Cir. 2007) indicated that section 156(e)(2) gives the Director the authority to extend a patent's term beyond that provided for by section 154 when the patent for which a term extension is sought "would expire before a certificate of extension is. . . denied" (citing section 156(e)(2)). In *Somerset*, the court held that the USPTO has no statutory authority to issue an interim extension when the underlying application for PTE is denied. Therefore, should the USPTO deny the PTE for the '932 patent, where extension is sought based on the regulatory review period for VUSION®, the previous interim extensions granted pursuant to section 156(e)(2) would be vacated *ab initio*.

Requirement to Show Cause

The Applicant of the PTE for the '932 patent is required to show cause why the PTE for the '932 patent should not be denied based on the apparent ineligibility as discussed *supra*. Specifically, any response should address (1) how the claims of the '932 patent claim the "product" as that term is defined in 35 U.S.C. § 156(f) and interpreted in *In re Alcon* and *Arnold P'ship v Dudas*, as discussed *supra* and (2) why the previously granted interim extensions pursuant to 35 U.S.C. § 156(e)(2) should not be vacated *ab initio* as improperly granted based on the apparent ineligibility of the PTE since the USPTO had no authority to grant the interim extensions as set forth in *In re Alcon, In re Reckitt,* and *Somerset Pharmaceuticals, inc. v. Dudas* as discussed *supra*.

Time Period For Response

A response to this order to show cause may be made if filed by the applicant within TWO MONTHS of the mailing date of this letter. The period for response may NOT be extended pursuant to 37 C.F.R. 1.136. A failure to respond to this letter will result in denial of the PTE accompanied by a vacatur of the previously granted interim extensions.

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

RE: VUSION® Ointment
FDA Docket No.: 2007E-0035

Approved NDAs with Zinc Oxide as Active Ingredient

Appl Type	*Appl No*	*Trade Name*	*Approval*	*Ap Date*
N	19	LAN-O-DERM ONT	APPEF	10/20/1938
N		SAL-O-GEN COMBINE CRM	APPEF	10/20/1938
N		SAL-O-GEN COMBINE LIQ	APPEF	10/20/1938
N	52	HOLDENS ONT	APPEF	10/12/1938
N	284	CLOVER PILE ONT	APPEF	1/25/1939
N	295	CLARANOL OINTMENT	APPEF	2/8/1939
N		CLARANOL SOAP	APPEF	2/8/1939
N	309	ZINCAD SALICHTHOL ONT	APPEF	2/9/1939
N	311	CRURICAST BANDAGES DRE	APPEF	10/6/1939
N	364	PELLISAN POWDER	APPEF	1/21/1939
N	378	CALA-DERMA LOTION	APPEF	2/21/1939
N	420	BIRNASAN ONT	APPEF	2/14/1939
N	451	DERMOTUBE A ONT	APPEF	2/21/1939
N	520	ENZO-CAL LOT	APPEF	3/8/1939
N	593	PRIVATE FORMULA NY POST HOSPITAL ZINC OXIDE	APPEF	3/22/1939
N	614	NONSPI CRM	APPEF	3/18/1939
N	688	CALAZOX ONT	APPEF	4/17/1939
N	689	B-E-Z ONT	APPEF	4/17/1939
N	767	KURTO LIQ	APPEF	4/27/1939
N	797	BURNBALM CRM	APPEF	6/13/1939
N	849	LORISAN-LYSS ONT	APPEF	5/3/1940
N	860	STAFENOL ONT	APPEF	10/17/1939
N	922	MARVAN SLV	APPEF	12/21/1939
N	1040	CAL-TAR LOT	APPEF	7/17/1939
N	1164	NOLAFENE ONT	APPEF	8/1/1939
N	1175	KINGS ONT	APPEF	7/15/1939
N	1181	PRIVATE FORMULA ONT	APPEF	8/22/1939
N	1184	FOOT BATH PWR	APPEF	11/6/1939
N	1204	T L ONT FOR SUPERFICIAL BURNS	APPEF	8/15/1939
N	1211	GYPSOLENE	APPEF	1/13/1940
N		GYPSOLENE SKIN LOT	APPEF	5/22/1940
N	1254	SANI-SOLESDRESSING	APPEF	7/19/1939
N	1394	EBROUILLETS ONT	APPEF	9/19/1939
N	1597	OTAMMA ONT	APPEF	9/11/1939
N	1726	ENZO-CAL CRM	APPEF	10/21/1939
N	1750	PETERSONS WHITE SLV	APPEF	2/13/1940
N	1790	NODOR LIQ	APPEF	11/8/1939
N	1810	FACIAL ONT	APPEF	1/13/1940
N	1813	DR GOSHORNS GOLDEN	APPEF	1/5/1940
N	1936	SESA-CREME A-1 OINTMENT	APPEF	1/30/1940
N	2129	EDMONDS ONT	APPEF	11/5/1940

Appl Type	Appl No	Trade Name	Approval	Ap Date
N	2231	ECZEMOL ONT	APPEF	6/6/1940
N	2247	GLENS SKIN AID LIQ	APPEF	4/17/1940
N	2397	UNCLE JOHNS OLD RELIABLE RTL ONT	APPEF	5/21/1940
N	2470	PRIVATE FORMULA PWR	APPEF	5/11/1940
N	2476	MEDEX ONT	APPEF	7/13/1940
N	2491	#42 I H C RTL ONT	APPEF	7/13/1940
N	2493	QUITZ ONT	APPEF	8/19/1940
N	2609	JOSETTES MAGIC DEODERANT PWR	APPEF	6/8/1940
N	2686	EVRONS RECTAL OINTMENT	APPEF	2/21/1942
N	2687	EVRONS RECTAL SUPPOSITORY	APPEF	2/21/1942
N	2757	THAYERS EXTERNAL LOT	APPEF	10/21/1940
N	2780	SCHLUETERS PINK ONT	APPEF	9/18/1940
N	2790	HERISAN ONT	APPEF	10/2/1940
N	2983	3-WAY POWDER	APPEF	10/31/1940
N		3-WAY SOLUTION	APPEF	10/31/1940
N	3043	DRIZON ONT	APPEF	9/23/1940
N	3083	ON-THE-SPOT HOUSEHOLD SLV	APPEF	11/19/1940
N	3254	E-B-Z COMPOUND ONT	APPEF	11/27/1940
N	3261	AMMENS POWDER	APPEF	12/18/1940
N	3456	MORKAZO ONT	APPEF	10/17/1941
N	3549	AL SUBACETATE W/ ZINC OXIDE ONT	APPEF	1/30/1941
N	3676	CHAF-O ONT	APPEF	4/16/1941
N	3730	RIGIDTEST SURG DRE	APPEF	10/1/1941
N	3739	DR HETMANS PWR	APPEF	5/3/1941
N	3753	RX 1973-DR. WG BENJAMIN LIQ	APPEF	4/8/1941
N	4058	RX 1988 DANIELSON MEDICAL ARTS PHARM ONT	APPEF	6/27/1941
N	4329	ON THE SPOT HOUSEHOLD SALVE	APPEF	10/22/1941
N	4427	LIQUIDEZE LIQ	APPEF	12/4/1941
N	4510	BEST BUDDY FOOT POWDER	APPEF	6/24/1942
N	5100	SULFATHIAZOLE ONT	APPEF	10/6/1942
N	5762	STERILITE ALPHA PWR	APPEF	3/6/1946
N	5769	INTRADERM TYROTHRICIN	APPEF	6/8/1951
N	6139	SURFACAINE	APPEF	6/15/1949
N		SURFACAINE	APPEF	9/2/1952
N		SURFACAINE	APPEF	7/14/1952
N		SURFACAINE	APPEF	11/27/1951
N		SURFACAINE	APPEF	2/21/1951
N		SURFACAINE	APPEF	11/29/1949
N		SURFACAINE	APPEF	3/21/1955
N		SURFACAINE	APPEF	4/27/1949
N		SURFACAINE	APPEF	2/1/1949
N		SURFACAINE	APPEF	5/28/1948
N		SURFACAINE	APPEF	5/11/1948
N		SURFACAINE	APPEF	4/8/1948

Appl Type	Appl No	Trade Name	Approval	Ap Date
N	6139	SURFACAINE	APPEF	7/30/1947
N		SURFACAINE	APPEF	12/15/1949
N		SURFACAINE AND SULFADIAZINE	APPEF	4/27/1949
N	6340	HISTADYL	APPEF	11/16/1949
N		HISTADYL	APPEF	11/15/1949
N		HISTADYL	APPEF	11/7/1950
N		HISTADYL	APPEF	12/9/1948
N		HISTADYL	APPEF	6/11/1948
N		HISTADYL	APPEF	11/10/1947
N		HISTADYL	APPEF	10/16/1952
N		HISTADYL	APPEF	2/10/1948
N		HISTADYL #38 0.5% SOL	APPEF	6/18/1951
N		HISTADYL AND ASA COMPOUND	APPEF	11/10/1949
N		HISTADYL AND SURFACAINE	APPEF	6/19/1951
N		HISTADYL AND SURFACAINE	APPEF	8/4/1952
N		HISTADYL AND SURFACAINE	APPEF	2/21/1951
N		HISTADYL AND SURFACAINE	APPEF	5/20/1949
N		HISTADYL AND SURFACAINE	APPEF	6/3/1949
N		HISTADYL COMPOUND WITH EPHEDRINE AND CODEI	APPEF	9/28/1949
N		HISTADYL COMPOUND WITH EPHEDRINE AND CODEI	APPEF	1/9/1950
N		HISTADYL CRM	APPEF	2/21/1951
N		HISTADYL CRM	APPEF	6/18/1951
N		HISTADYL E.C.	APPEF	12/5/1951
N		HISTADYL HCL	APPEF	4/30/1948
N		HISTADYL HCL AND EPHEDRINE HCL	APPEF	6/4/1948
N		HISTADYL HCL, 2% AND SURFACAINE, 0.5%	APPEF	7/6/1948
N		HISTADYL HCL, 2% AND SURFACAINE, 0.5%	APPEF	1/18/1949
N		HISTADYL HYDROCHLORIDE 0.5% OPHTALMIC ONT	APPEF	9/9/1948
N		SURFADIL	APPEF	3/31/1954
N	7516	ANTOPIC CRM	APPEF	8/14/1950
N	7588	TRIMETON MALEATE W/ NEOCALAMINE LOT	APPEF	4/25/1951
N	7631	INHISTON / PREPARED NEOCALAMINE LOT	APPEF	8/18/1950
N	7943	QUOTANE	APPEF	3/7/1952
N	8056	DICAINAL	APPEF	8/9/1951
N	8981	DERMAVAL	APPEF	8/28/1953
N	8982	REXALL MEDICATED DUSTING PWR	APPEF	12/24/1953
N	9075	RD EUDICALMA W/ ANTIHISTAMINE AND BENZOCAIN	APPEF	10/30/1953
N	9076	RD EUDICALMA W/ ANTIHISTAMINE AND BENZOCAIN	APPEF	10/27/1953
N		RD EUDICALMA W/ ANTIHISTAMINE AND BENZOCAIN	APPEF	1/27/1954
N	9163	ANTI-CAL LOTION	APPEF	3/23/1954
N	9351	CAL-HIST LOTION	APPEF	5/20/1954
N	9874	TRONOLEN	APPEF	5/24/1955
N		TRONOLEN	APPEF	10/2/1957
N	10541	BY-NA-MID	APPEF	2/7/1957

Appl Type	Appl No	Trade Name	Approval	Ap Date
N	10541	BY-NA-MID	APPEF	10/16/1958
N		BY-NA-MID	APPEF	9/6/1962
N		BY-NA-MID	APPEF	9/4/1963
N	10777	METASHAL LOTION	APPEF	3/29/1957
N		METASHAL OINTMENT	APPEF	3/29/1957
N	11571	BITUPAL CREAM	APPEF	2/9/1959
N		BITUPAL OINTMENT	APPEF	2/9/1959
N	11688	BITUPAL-HC	APPEF	1/8/1959
N		BITUPAL-HC	APPEF	11/3/1959
N	11739	DIAKET LIQUID	APPEF	9/8/1959
N		DIAKET POWDER	APPEF	9/8/1959
N		DIAKET SOLVENT LIQUID	APPEF	9/8/1959
N	12261	NATOREXIC TAB	APPEF	10/10/1960
N	21026	VUSION	APPEF	2/16/2006